on a formulation according to claim 1.

13. (New) A method according to claim 12, wherein said disorder is selected from age-related osteoporosis, osteoporosis associated with post-menopausal hormone status, primary and secondary hyperparathyroidism, disuse osteoporosis, diabetes-related osteoporosis, glucocorticoid-related osteoporosis, benign prostatic hyperplasia and prostate cancer.

REMARKS

The foregoing amendments to the specification and the claims are requested to enter sequence ID numbers into the application.

Also, new claims 7-13 have been added to the above-identified application as set forth above. These claims were added during PCT prosecution in the parent International Application. Therefore, it is requested that these claims now be incorporated in the present application and that no new matter has been added. Applicants also respectfully request that the foregoing amendments be made prior to examination of the present application.

Applicant believes that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date: December 26, 2001

By _____

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Version with Markings to Show Changes Made

IN THE SPECIFICATION:

Please replace the paragraph beginning on page 1 at line 23 with the following rewritten paragraph:

We have now found that GnRH-II has an important role in the function of a number of organs. For example, it influences osteogenesis and it modulates the proliferation of prostatic epithelial cells. Accordingly, we have considered the means by which this agent and its analogues might usefully be delivered in a clinical situation, and it is an object of the present invention to provide suitable formulations for achieving this purpose. The formulations according to the present invention rely on the use of a biodegradable polymer to hold the peptide in a depot, from which it is released into the systemic circulation at a controlled rate. These formulations comprise two key elements, the biologically active peptide and the biodegradable polymer. The biologically active peptide is a decapeptide according to the sequence (SEQ ID NO: 7).

Please replace the paragraph beginning on page 4 at line 3 with the following rewritten paragraph:

In a second aspect, the invention as disclosed herein comprises a method for the treatment of an individual suffering from a disorder of bone or prostate growth, or considered to be at risk of so suffering. This method fo treatment comprises the administration to said individual of a therapeutically effective amount of a formulation containing, as an active principal, a peptide according to the sequence (SEQ ID NO: 7).

Please replace the paragraph beginning on page 6 at line 27 with the following rewritten paragraph:

Microencapsulated formulations can be prepared either from the solid peptide (as a powder) or from a solution, and particularly an aqueous solution, of the peptide. The polymer is first dissolved in a suitable organic solvent. The peptide is then added to this solution and the mixture is vigorously stirred to disperse the peptide in the organic phase. A second organic solvent is then added. This second solvent is chosen to reduce the solubility of the polymer in the organic phase. The polymer comes out of solution to form a coating around the particles of solid peptide (SEQ ID NO: 6)

(or around the droplets of dispersed aqueous solution). The resultant microcapsules are then hardened by washing to remove traces of the organic solvents. They are then ready to be suspended in an appropriate liquid for administration.

Please replace the paragraph beginning on page 9 at line 6 with the following rewritten paragraph:

1B. Cleavage and deprotection (SEQ ID NO: 6).

IN THE CLAIMS:

1. (Amended) A pharmaceutical formulation for the controlled release of a therapeutic peptide or a salt thereof, which peptide has the sequence (SEQ ID NO: 7)

pyro Glu-His-Trp-Ser-Xaa^1-Gly-Xaa^2-Xaa^3-Pro-Gly-NH_2

wherein Xaa^1 is His or Tyr,

Xaa^2 is Trp or Leu, and

Xaa^3 is Tyr or Arg,

provided that when Xaa^1 is Tyr and Xaa^2 is Leu, then Xaa^3 is not Arg,

and which formulation further comprises a pharmaceutically acceptable biodegradable polymer.

2. (Amended) The pharmaceutical composition according to Claim 1, wherein the peptide is (SEQ ID NO: 6)

pyroGlu-His-Trp-Ser-His-Gly-Trp-Tyr-Pro-Gly-NH_2